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EXAMINER	
WILSON, MICHAEL C	

ART UNIT	PAPER NUMBER
1632	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/284,114	SAKAGUCHI, SHIMON	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13,18,21 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13 18 21 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Applicant's arguments filed 4-22-03, paper number 28, have been fully considered but they are not persuasive. Claims 10-12, 14-17, 19 and 20 have been canceled. Claims 21 and 22 have been added. Claims 13, 18, 20 and 21 are pending and under consideration in the instant office action. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

The requirements for deposit ATCC accession No. BP-7790 have not been met. The deposit information of SKG embryos provided 2-7-02, paper number 18, does not fulfill the deposit requirements. The deposit information states the SKG embryos were originally deposited 11-6-02, but applicants have not provided a declaration indicating the chain of custody was maintained since the time of filing. The declaration by Dr. Sakaguchi filed 4-22-03 states the mice of deposit BP-7790 are those described on pg 3, lines 6-7, of the specification. However, pg 3, lines 1-7, states

"[a]s a result of his extensive study for solving the problems described above, the present inventor found a mouse with joint swelling among a normal BALB/c colony, and from this finding, attained the present invention. Hence, the present invention is a mouse strain having the character of natural onset of autoimmune arthritis. This mouse strain was designated as the SKG strain."

Pg 3, lines 1-7, does not describe the embryos deposited because it is a discussion generic to at least five types of mice disclosed in the specification in Example 1 (pg 5-6), each of which has a different genotype/phenotype, i.e. BALB/c mice, the founder mouse, 1st generation (backcrossed with BALB/c mice), 2nd generation (backcrossed with BALB/c mice), and 3rd generation mice (backcrossed with BALB/c mice).

Therefore, the declaration does not fulfill the deposit requirement by providing which of the numerous mice disclosed in the specification, having different genotypes and different symptoms of arthritis that were specific to the genotype, were used to make the SKG strain deposited as BP-7790. In addition, pg 3, lines 1-7, does not teach the SKG strain had rheumatoid arthritis or genes that cause natural onset of arthritis as claimed. As such, the requirements for deposit BP-7790 have not bee met.

Summary of the invention

Applicants disclose a founder female derived from BALB/C mice having joint swelling (pg 4, Example 1), a first generation obtained from breeding the founder female with a BALB/C mouse, 4/12 of which have joint swelling (pg 5, line 1), a second generation obtained from breeding a first generation mouse (having joint swelling) with a BALB/c mouse, wherein 6/15 of the second generation had joint swelling, and a third generation obtained from breeding a second generation mouse (having joint swelling) with a BALB/c mouse, wherein 10/28 of the third generation had joint swelling (pg 5, 1st para.).

It was determined "in later experiments, the BALB/c mice considered normal and apparently free of swelling in large joints (e.g. leg joints), were found by detailed observation for a long period (6 months or more) to have joint swelling in small joints of the fingers" (pg 5, lines 22-26). The specification states the incidence of arthritis was 100% taking into account large or small joint arthritis (para. bridging pg 5-6); it assumed this statement refers to BALB/c mice. The specification states "[b]y later experiments on the inheritance in a large scale, it was reasonably estimated that the genetic abnormality causing the natural onset of autoimmune arthritis is autosomal and recessive. The SKG mice are therefore maintained at present as homozygotes. Their incidence of arthritis is almost 100%, and the penetrance of the genetic abnormality in the homozygous is considered to be almost 100% in the environment where they are currently maintained" (pg 6, lines 3-8). Overall, the specification does not describe which generation of mice are the SKG strain, which mice were used to make the embryos deposited as BP-7790, or the genotype/phenotype of the SKG strain or the mouse strain deposited as BP=7790.

Claim Rejections - 35 USC § 101

I. Claims 13, 18, 21 and 22, as newly amended, are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 13 and 21, as newly amended, require a "mouse derived from a mouse strain homozygous for the genes causing the natural onset of rheumatoid arthritis, wherein an embryo of the mouse is deposited as accession no. FERM BP-7790".

Claims 18 and 22, as newly amended, are directed toward a method of producing a "mouse strain, deposited as accession no. FERM BP-7790... ...being homozygous for the genes causing the natural onset of rheumatoid arthritis...." The mouse in claims 13 and 21 is a naturally occurring product, and the method of claims 18 and 22 is a naturally occurring process. Therefore, the claims are non-statutory subject matter.

Claims 13 and 21 are interpreted as encompassing any mouse homozygous for any genes causing rheumatoid arthritis. The limitation that "an embryo of the mouse is deposited" does not alter the structure and function of the mouse claimed. Nor are the claims limited to mice derived from the embryo deposited. Therefore, the phrase "wherein an embryo of the mouse is deposited..." does not bear patentable weight. Claims 18 and 22 require producing a mouse strain deposited as accession no.... ...being homozygous for the genes causing the natural onset of rheumatoid arthritis" by repeated mating between mice in any maintained colony to produce offspring; and screening for signs of arthritis. Nordling of record (1992, Arthritis and Rheumatism, Vol. 35, pg 717-722) taught breeding BALB/c mice and screening the offspring, wherein the offspring had symptoms of rheumatoid arthritis in joints of the foot. Thus, the mice derived naturally from the BALB/c strain had symptoms of rheumatoid arthritis in joints of the foot (pg Table 1, see BALB/c, male). Without evidence to the contrary, the naturally occurring mice are "homozygous" for the genes causing arthritis because the mice showed signs of disease, because the onset of arthritis is "natural" and because the patent office does not have the means to determine the genotype of the mice.

Therefore, the claims are equivalent to naturally occurring BALB/c mice and process of breeding BALB/c mice and are non-statutory subject matter.

New Matter

II. Claims 13 and 18, as newly amended, remain rejected and claims 21 and 22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 13 as amended is new matter. Claim 13 requires a "mouse derived from a mouse strain homozygous for the genes causing the natural onset of rheumatoid arthritis." Nowhere does the specification contemplate the gene causing the natural onset of rheumatoid arthritis. Claim 13 requires "wherein an embryo of the mouse strain is deposited as accession no. FERM BP-7790...." Nowhere does the specification contemplate a "mouse strain homozygous for the gene causing the natural onset of rheumatoid arthritis" or that such a mouse was equivalent to the embryo deposit of BP-7790. The specification does not suggest any genes that cause natural onset of arthritis. Nor does the specification teach what type of mouse was bred with the "mouse strain homozygous..." to obtain "an embryo of the mouse strain" deposited as BP-7790. Applicants specifically point to pg 6, lines 3-10. The specification states "[b]y later experiments on the inheritance in a large scale, it was reasonably estimated that the genetic abnormality causing the natural onset of autoimmune arthritis is autosomal and

recessive. The SKG mice are therefore maintained at present as homozygotes. Their incidence of arthritis is almost 100%, and the penetrance of the genetic abnormality in the homozygous is considered to be almost 100% in the environment where they are currently maintained" (pg 6, lines 3-8). The citation does not support the claim because it does not teach how the SKG mice were obtained, the genes that caused arthritis, the generation of mice that were used for deposit, or the generation of mice that resulted in homozygotes having arthritis as claimed.

Applicants point to Examples 2-9 and Figures 1, 3, 5, 7, 9, 11, and 13-16. Such a response is inadequate and not does constitute support for the newly added limitations in the disclosure as originally filed because it is generic to the remainder of the specification. As set forth in 37 CFR 1.121(b)(2)(iii): Each amendment when originally submitted must be accompanied by an explanation of the support in the disclosure of the patent for the amendment along with any additional comments on page(s) separate from the page(s) containing the amendment. Applicants have not explained how Examples 2-9 and Figures 1, 3, 5, 7, 9, 11, 13-16, support claim 13. However, to expedite prosecution, Examples 2-9 and Fig. 1, 3, 5, 7, 9, 11, 13-16, have been reviewed, and support for the mouse claimed cannot be found. In future responses, failure to point to support for amendments by page and line number along with an explanation of how the citation supports a limitation in the claim will be considered non-responsive.

Claim 18 as amended is new matter. The specification did not contemplate "mating between a maintained colony to produce offspring" or "screening the offspring

for the trait of developing natural onset of rheumatoid arthritis" as broadly claimed to produce a mouse strain deposited as an embryo. Example 1 (pg 5-6) teaches breeding BALB/c mice and obtaining a founder female, breeding the founder female with BALB/c mice, and breeding 1st and 2nd generation mice with BALB/c mice. Each generation had different genotypes and phenotypes. For example, only some had arthritis in small joints. Example 1 does not teach whether the embryos deposited correlate to the founder mouse, the 1st, 2nd or 3rd generation mice. The teachings in the specification are limited to specific breedings that resulted in generations of mice having specific genotypes and phenotypes. The specification did not contemplate breeding any mice as broadly claimed to obtain the "mouse strain" having arthritis as claimed or to obtain the embryos used for deposit as claimed. Applicants have not explained how Examples 1-9 and Fig. 1, 3, 5, 7, 9, 11 and 13-16 support claim 18.

Claims 21 and 22 are new matter. Applicants point to Example 3, lines 25-27; however, Example 3 (pg 6, line 22, through pg 7, line 1) does not have 25 lines. Applicants point to Examples 5-9, Figures 5, 7 and 9. Applicants have not explained how Examples 5-9 or Fig. 5, 7 or 9 correlate to the claimed invention. The specification does not teach a mouse having any symptom or combination thereof as claimed or that an embryo equivalent to a mouse having the breadth of symptoms was used for deposit.

Written description

III. Claims 13 and 18, as newly amended, remain rejected and claims 21 and 22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 13, 18, 21 and 22 require the limitation of "ATCC accession No. BP-7790". The deposit information of SKG embryos provided 2-7-02, paper number 18, does not fulfill the deposit requirements. While the deposit information states the SKG embryos were originally deposited 11-6-02, applicants have not provided a declaration indicating the chain of custody was maintained since the time of filing. Applicants provide a declaration by Dr. Sakaguchi stating the mice of deposit BP-7790 are those described on pg 3, lines 6-7, of the specification. However, pg 3, lines 1-7, of the specification states

"[a]s a result of his extensive study for solving the problems described above, the present inventor found a mouse with joint swelling among a normal BALB/c colony, and from this finding, attained the present invention. Hence, the present invention is a mouse strain having the character of natural onset of autoimmune arthritis. This mouse strain was designated as the SKG strain."

Pg 3, lines 1-7, does not describe the embryos deposited because it is a discussion generic to at least five types of mice disclosed in the specification in Example 1 (pg 5-6), each of which has a different genotype, i.e. BALB/c mice, the founder mouse, 1st generation (backcrossed with BALB/c mice), 2nd generation (backcrossed with BALB/c mice), and 3rd generation mice (backcrossed with BALB/c mice). The declaration does

not point to a specific mouse described in the specification or describe the genotype or phenotype that is specific to the embryo deposited. Pg 3, lines 1-7, does not teach the SKG strain had rheumatoid arthritis or genes that cause natural onset of arthritis as claimed. The genotype of the SKG strain cannot be determined from pg 3, lines 1-7, or how it was obtained. As such, the specification does not adequately describe the genotype or phenotype of the SKG strain or of the embryos deposited as BP-7790.

Claim 13 lacks written description. Nowhere does the specification describe i) the genotype or phenotype of a "mice strain homozygous for... ... arthritis" or ii) depositing embryos "of the mouse strain homozygous for... ...arthritis" as claimed. The only mention of a homozygous mouse in on pg 6, line 6-7, which states the "SKG mice are therefore maintained at present as homozygotes." However, the genotype and phenotype of SKG mice is not described. It cannot be determined if the "mouse strain homozygous... ...for arthritis" as claimed is equivalent to the BALB/c mice, the founder mouse, the 1st, 2nd, or 3rd generation mice described in the specification which all have natural onset of rheumatoid arthritis. Without evidence to the contrary, the BALB/c mice, the founder mouse, the 1st, 2nd, or 3rd generation mice all are homozygous for some gene that causes natural onset of arthritis because they all have natural onset of arthritis. Therefore, the specification does not adequately describe i) the genotype and phenotype of the mice encompassed by genus of mice claimed, ii) which generation of embryos were deposited as BP-7790, ergo, the phenotype and genotype of the embryos deposited, or iii) the genes that cause "natural onset of rheumatoid arthritis" as claimed.

Claim 18 lacks written description. The specification did not describe mating between any "maintained colony" as broadly claimed to produce offspring or "screening the offspring for the trait of developing natural onset of rheumatoid arthritis" as broadly claimed to produce a mouse strain deposited as an embryo. Example 1 (pg 5-6) teaches breeding BALB/c mice and obtaining a founder female, breeding the founder female with BALB/c mice, and breeding 1st and 2nd generation mice with BALB/c mice. Each type of mouse has different a genotype and phenotype as discussed throughout example 1. The only maintained colonies described were BALB/c mice and possible mutants thereof. In addition, the specification does not describe which of the number of breedings described in Example 1 produced the mouse strain deposited as BP-7790. Therefore, it cannot be determined how to produce the mouse strain deposited as BP-7790 as claimed. Applicants have not explained how Examples 1-9 and Fig. 1, 3, 5, 7, 9, 11 and 13-16 support claim 18.

Claims 21 and 22 lack written description. The specification did not teach or suggest a mouse derived from an embryo of BP-7790 that had the genus of symptoms claimed. Different generations had different symptoms that were dependent upon their genotype and phenotype. Example 5 shows SKG mice had increased ankle size (pg 7). Example 6 shows SKG mice had increased IgM (rheumatoid factor) (pg 8, lines 1-6). It cannot be determined how an increased antibody against a bovine type II collagen is a test of autoantibodies or relevant to the claimed (Example 7; pg 8, lines 7-13). Examples 8 shows SKG mice had hypergammaglobulineamia (pg 8, lines 14-20). Example 9 shows stimulating spleen and lymph node cells from mice having arthritis *in*

vitro, but the significance cannot be determined. The specification provides no correlation between the symptoms in Examples 5-9 and "arthritis in a foreleg or hind leg joint, joint stiffening, appearance of a pannus, lymphocyte infiltration into joint cartilage or bone, destruction of joint cartilage or bone, production of rheumatoid factor or autoantibody against type II collagen, hypergammaglobulinemia" or that any animal has any combination thereof as broadly claimed.

Indefiniteness

IV. Claims 10-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of the mouse in claim 13 cannot be determined. It is unclear if the mouse claimed is "homozygous for genes causing the natural onset of rheumatoid arthritis" or if only the mouse strain used to "derive" the mouse is "homozygous for genes causing the natural onset of rheumatoid arthritis." It is unclear if the mouse claimed or the "mouse strain" is derived from embryos deposited as BP-7790. It is unclear whether the claim merely requires the "mouse strain" has produced embryos that were deposited as BP-7790. Overall, the nexus between the "mouse," the "mouse strain," the genotype (homozygous for genes causing... ...arthritis), and the embryos deposited as BP-7790 cannot be determined. In addition, the nexus between the mouse claimed, the embryos deposited as BP-7790 and the various types of mice described in the specification cannot be determined. In particular, it cannot be

determined which breeding described in the specification was used to obtain embryos for the deposit. The breeding described in Example 1 (pg 5-6) is essential to the invention as each breeding described in the specification resulted in mice with a different genotype and phenotype (see summary of the invention above). Next, the metes and bounds of "genes causing the natural onset of arthritis" cannot be determined. None are described in the specification or in the art at the time of filing. Finally, the metes and bounds of what applicants consider a "natural" onset of arthritis cannot be determined. If the hand of man is required for breeding particular mice to obtain the desired phenotype and genotype, such a process cannot be considered to result in a "natural onset" of arthritis. Therefore, the term "natural" in context of the invention does not make sense. Clarification is required.

Claim 18 does not clearly set forth the steps required to obtain a mouse strain deposited as BP-7790. Repeated mating between mice in a maintained colony to produce offspring, and "screening the offspring for the trait of developing natural onset of rheumatoid arthritis" does not result in producing a mouse strain deposited as BP-7790. Screening for arthritis does not clearly set forth the mice develop rheumatoid arthritis. The breeding described in Example 1 (pg 5-6) is essential to the invention as each breeding described in the specification resulted in a generation of mice with a different genotype and phenotype (see summary of the invention above). The nexus between the mating step in the claim and the numerous matings described in Example 1 (pg 5-6) cannot be determined. Therefore, the mice required for "repeated mating" to obtain a mouse strain deposited as BP-7790 cannot be determined.

Claim Rejections - 35 USC § 102

The rejection of claims 12, 14-17, 19 and 20 under 35 U.S.C. 102(b) as being anticipated by Nordling of record (1992, Arthritis and Rheumatism, Vol. 35, pg 717-722) has been withdrawn because the claims have been canceled.

The rejection of claims 12, 14-17, 19 and 20 under 35 U.S.C. 102(e) as being anticipated by Yamanaka et al. (US Patent 4,950,741) has been withdrawn because the claims have been canceled.

V. Claims 13, 18, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Nordling of record (1992, Arthritis and Rheumatism, Vol. 35, pg 717-722).

Nordling taught mice derived from the BALB/c strain having symptoms of rheumatoid arthritis in joints of the foot (pg Table 1, see BALB/c, male). Without evidence to the contrary, the mice are "homozygous" because the mice showed signs of disease and because the patent office does not have the means to determine the genotype of the mice. In addition, the metes and bounds of the mice in claim 13 are unclear (see 112/2nd above). Mating two BALB/c mice is equivalent to "repeated mating between mice in a maintained colony" (claim 18). Detecting arthritis in the foot joint is equivalent to a symptom of rheumatoid arthritis (claim 20) and for screening for natural onset of rheumatoid arthritis in a leg joint (claim 21).

VI. Claims 13, 18, 21 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Yamanaka et al. (US Patent 4,950,741).

Yamanaka taught a breeding BALB/c mice and obtaining a BALB/c mouse that developed antibodies against a rheumatoid arthritis-specific protein, which is a trait of rheumatoid arthritis. The trait is "natural onset" because the antibodies are a result of the mouse's natural immune system. Without evidence to the contrary, the mice are "homozygous" because the mice showed signs of disease and because the patent office does not have the means to determine the genotype of the mice. In addition, the metes and bounds of the mice in claim 13 are unclear (see 112/2nd above). Mating two BALB/c mice is equivalent to "repeated mating between mice in a maintained colony" (claim 18). Detecting antibodies against a rheumatoid arthritis-specific protein is equivalent to a symptom of rheumatoid arthritis (claim 20) and for screening for production of rheumatoid factor (claim 21).

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson

MICHAEL WILSON
PRIMARY EXAMINER